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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,601	11/15/2001	Philippe Moullier	216143US0DIV	7765

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/987,601	MOULLIER ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-91* is/are pending in the application.

4a) Of the above claim(s) *72-91* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/532,814* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 61-91 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I in the amendment filed on 8/27/03 is acknowledged. The traversal is on the ground(s) that the method of Group II, for example, claim 72, can only be accomplished by introducing an implant into the mammalian host. Applicants further argue that there is no evidence to show that the implant of Group I can be used to deliver a medication, and the method for treating a disease of Group III can be accomplished by administering a pharmaceutical compound. In addition, Applicants argue that there are no reasons to support that the inventions of Groups II and III are patentably distinct. Moreover, Applicants argue that the search of entire application can be made without serious burden. Lastly, Applicants request the rejoinder of Group II to Group I when the product claims are found allowable.

The above arguments are found not persuasive for following reasons. The invention of Groups I-III are patentably distinct for reasons clearly set forth of the record mailed on 7/29/03. In response to Applicants argument, claim 72 is drawn to a method of administering cells to a mammalian host, not a method of introducing implant into mammalian host. Methods for introducing cells to a mammal is well known in the art, direct injection is one of those methods of introducing cells to a mammalian host (for example, direct injection of tumor cells to nude mice to induce tumor formation). Therefore, the inventions of Group I and II are patentably distinct.

The method of treating a disease as claimed in Group III can be accomplished by administering a chemical compound to the host. Treating a disease by a pharmaceutical compound is common practice in the art. For instance, treating headache with oral administration of Tylenol. This method does not involve use the implant of Group I. A chemical compound is chemically, biologically distinct from the implant comprising cells as recited in the claims of Group I. Therefore, the inventions of Group I and Group III are patentably distinct from each other.

The reasons for patently distinctiveness between Groups II and III are clearly discussed in the previous office action. Each invention has distinct purpose and requires different method steps to accomplish such purpose. Therefore, the inventions are patentably distinct. A search of one group is not co-extensive as the search of another, and would have been burdensome. Therefore, the requirement is still deemed proper and is therefore made FINAL.

The request for rejoinder of Groups I and II is not considered at present because the product claims are not in allowable condition.

Accordingly, claims 72-91 are withdrawn from consideration for being directed to non-elected subject matter. Claims 61-71 are currently under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08,360,801, filed on 5/11/94.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 61, 66-71 are rejected under 35 U.S.C. 102(a) as being anticipated by Verma et al (WO 92/15676).

Verma et al. disclose a method for gene therapy wherein genetically modified fibroblasts are anchored on a biocompatible matrix support and implanted into an animal (see page 3-4 and page 16). Verma et al. further disclose that use of autologous cell would minimize the possibility of rejection (see page 4, line 27-28). Verma et al. also disclose that factors promoting angiogenesis such as bFGF is included in the implantation for ensure rapid vascularization of the grafted implant (see page 16, lines 25-27). Finally, Verma et al. disclose a method of introducing a viral vector expressing human factor IX into mouse embryonic fibroblast, subsequent anchoring of the cells to a collagen matrix, and further implanting said implant into a mouse (see figure 3 and example II). Verma et al. disclose the inserted implants are extensively vascularized and the implanted MEFs secret human factor IX into circulation. Therefore, Verma et al. disclose the instantly claimed inventions.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Moullier et al. (1992).

Moullier et al. disclose a method for gene therapy wherein fibroblast expressing B-glucuronidase is anchored to PTFT fibers and implanted into mouse. Moullier et al. further disclose the implanted cells expressing the enzyme and secret it to distant organs (see abstract). Therefore, Moullier et al. disclose the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verma et al., in view of Damien et al. (US5, 563,124).

The teaching of Verma et al. is discussed above. However, Verma et al. do not teach that the biocompatible support is a calcium based material or coral.

Damien et al. teach a product which includes calcium carbonate and bone growth factor useful for promotion of bone formation when implanted in the body (abstract). Damien et al. teach that the calcium carbonate from natural coral contains a network of macro and micropores that allow bone precursor cells and vessels to invade the coral and implant and provide a large surface for bone deposition, therefore, it is an ideal material for bone implant (see col. 2, lines 31-67, and col. 3, lines 1-4). Damien et al. further teach that the porosity of coral can vary from 0-50% (see col. 3, lines 5-18). Damien et al. also teach that the calcium carbonate can also be mixed with a gelling material such as collagen, fibrin or alginate to form a matrix (see col. 6, lines 41-42).

It would have been obvious to one of ordinary skill in the art to use the coral material as the biocompatible support matrix in for implanting the fibroblast cells expressing a gene of interest based on combined teaching of Verma et al. and Damien et al. For successful releasing the gene product to reach the desired site would require well vascularized tissue formation at the implant site, one of ordinary skill of art would have been motivated to use a support material that promote such vascularization. Damien et al. teach that the calcium carbonate from natural coral has such property and promote bone formation in vivo. As such, the ordinary artisan would be motivated to use such material for implantation of the fibroblast cells as taught by Verma et al. The skill of art in the field of tissue implantation is high, absent evidence from the contrary, one of ordinary skill of art would have reasonable of expectation of success to culture fibroblast on the coral and implant it in vivo. Therefore, the invention would have been obvious to one of ordinary skill of art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61-65 and 71 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 34 of U.S. Patent No. 5,906,817. Although the conflicting claims are not identical, they are not patentably distinct from each other because the biocompatible implant recited by claims 61-65 of the instant application would encompass the implant of claims 1 and 34 of U.S.5,906,817.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

JAMES KETTER
PRIMARY EXAMINER